DUPLICATE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service #25

Food and Drug Administration
Rockville MD 20857

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DEPUTY ASSISTANT
COMMISSIONER FOR PATENTS

MAR 28 1994

Re: LAMISIL CREAM
Docket No. 93E-0147

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,755,534 filed by Sandoz, Ltd. under 35 U.S.C. § 156. The patent claims the human drug product Lamisil Cream (terbinafine hydrochloride), NDA 20-192.

In the May 18, 1993 issue of the Federal Register (58 Fed. Reg. 28,984), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before November 15, 1993, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Robert S. Honor
Patent and Trademark Affairs
Sandoz Pharmaceutical Corporation
59 Route 10
E. Hanover, NJ 07936